IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ALASKA

RICHARD HELMS,)
Plaintiff,)
vs.) Case No. 3:11-cv-00186-SLG
UNITED STATES OF AMERICA,)
Defendant.)

DEPOSITION OF BRUCE WAPEN, M.D.

November 19, 2013

Taken By Gary M. Guarino

TIME SET: 10:30 a.m. PST

DURATION: 10:32 a.m. to 12:30 p.m. PST

LOCATION: Bay Area Executive Offices, Inc.
Airport Corporate Center
533 Airport Boulevard, Suite 400
Burlingame, California

Reported by Christine M. Niccoli, RPR, C.S.R. No. 4569

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I N D E X

EXAMINATION INDEX

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EXHIBIT INDEX

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BE IT REMEMBERED that, pursuant to Notice of Taking Deposition of Bruce Wapen, M.D., and on Tuesday, November 19, 2013, commencing at the hour of 10:32 a.m. PST thereof, at Bay Area Executive Offices, Inc., Airport Corporate Center, 533 Airport Boulevard, Suite 400, Burlingame, California, before me, CHRISTINE M. NICCOLI, a Certified Shorthand Reporter licensed by the State of California, there personally appeared

BRUCE DAVID WAPEN, M.D.,

whose business address is 969-G Edgewater Boulevard, No. 807, Foster City, CA 94404-3760, who is called as a witness by the Defendant herein and, having first taken an oath, is examined and testifies hereinafter.

MR. GUARINO: Hello, Christine, it's Gary Guarino from the U.S. Attorney's Office in Anchorage, Alaska. I'm calling for the deposition of Dr. Bruce Wapen, I believe.

THE COURT REPORTER: Yes. Wapen. We're all here ready to go, and Dr. Wapen has been sworn in.

MR. GUARINO: Okay, and who is there?

THE COURT REPORTER: Mr. Helms is here, Dr. Wapen, and myself, the court reporter.

MR. GUARINO: All right. Is this being

A. Okay.
Q. Have you ordered those types of scans in your experience?
A. Routinely.
Q. Okay. How long does it take for one of those exams to be ordered, for the patient to undergo the exam, and for the results to be interpreted by a radiologist?
A. About a half an hour.
Q. Okay. Does it sometimes take longer?
A. It may; but because of the time imperative with strokes, we now have what we call a Code Stroke, which is sort of like equivalent to the Code Blue for heart -- cardiopulmonary arrest.

And the Code Stroke then stops Radiology Department in their tracks, waiting for the patient to go directly from the Emergency Department after an initial evaluation to get the CT scan; and the radiologist then immediately reads the CT scan and calls the emergency physician back. So everything has been expedited to make this whole process go as quickly as possible.

Q. How long have you -- how long have you had that Code-Stroke process in place?
A. Yeah. That's been about two years.

Q. About two years?
A. Yes.
Q. From today?
A. Yes.
Q. All right. Do you know whether there was such a Code-Stroke process in place back in 2008 in Alaska?
A. I do not.
Q. And at the medical facility that you are at, do you have a radiologist on staff who's -- or someone who's available 24 hours a day?
A. Yes.
Q. Are they in the building 24 hours a day?
A. No. In the -- in the late evening, they go home, and then overnight until about 8 o'clock the next morning we have teleradiology. Now that all the images are digital, they can be sent anyplace in the world at the speed of light and read by radiologists immediately.

And again, if it's a stroke patient, rule out intracranial bleed, the -- the teleradiologists late at night are instructed to make this their highest priority.

Q. And are there any other tests that need to be done on a potential stroke patient prior to making a decision as to whether and how to treat them?

A. Well, there are a number of tests that are done, including a electrocardiogram, to make sure that their atrial fib is not going on, which would then make one think that maybe this were an embolic stroke, although that wouldn't preclude the use of tPA.

The -- A baseline coagulation study is done to make sure that they are not already in an anticoagulated state because of, let's say, liver failure from alcoholism, something of that nature.

But outside of those things, there are other studies that are done as part of the stroke protocol, but none of them would preclude the administration of tPA. The main exclusion would be the visualization of bleeding in the brain on a CT scan.

Q. So if did a CT scan and saw signs of hemorrhage, then that would be a counter indication [sic] for administering tPA?
A. Oh, absolutely.
Q. All right. Are there any other physical characteristics -- blood pressure, blood cell counts, blood sugar, anything like that -- that would be a counter indication for administering tPA?
A. Yes. So there's a list of contraindications which include a blood pressure systolic of higher than 185, such historical things as major surgery or major

trauma within the last three months of a previous stroke or within the last three months, concomitant use of other potent anticoagulation agents like Coumadin.

And that -- there's a list. It's about ten things, which I always have to scan through, keep it kind of in my pocket when I'm at work so that I don't miss one of the exclusion criteria.

Q. And you -- and the patient would have to be assessed for those exclusion criteria before a decision would be made as to whether to administer tPA?
A. Yes. But that's a very quick process other than the doing of the CT scan. The rest of those things is a very quick process.
Q. And, I take it, you don't have any personal knowledge about what the CT scan capability was at any of the medical facilities in Alaska in 2008?
A. I do not.
Q. And you don't have any personal knowledge as to how long it took any of those facilities to conduct CT scans on potential stroke patients back in August of 2008?
A. I do not.
Q. Now, assume that a patient has -- a potential stroke patient has a CT scan and that the finding is that it's an ischemic stroke.

Exhibit C
Pages as Marked

And just for the record, my understanding of ischemic stroke is a stroke that's caused by a blockage in blood flow. Is that correct?

A. That's correct.

Q. All right. And so assume that the scan finds evidence of ischemic stroke. Your report indicates that at that point, the standard of care would be for the treating physician to discuss the treatment options with the patient. Is that correct?

A. That is correct.

Q. And in fact, I'm looking at the bottom of page 3 of your report. Do you see that?

A. Yes.

Q. You say, "The standard of care in Emergency Medicine would have been to discuss the pros and cons of the use of the drug tPA with the patient and to administer that drug if the person chose that avenue of therapeutic intervention."

Did I read that correctly?

A. Yes.

Q. Okay. Would you explain to me what you meant by the pros and cons of the use of tPA.

A. Yes. So tPA it can -- is a double-edged sword. Used correctly, it has the potential to either improve the symptoms of the stroke or completely resolve

the symptoms of the stroke in about 12 percent above that which would happen in a person who received no treatment of any kind for his or her stroke.

Q. And let me make sure I understand what you're saying there; that some patients will have improvement or resolution even without tPA?

A. Correct.

Q. But that there's an additional 12 percent of patients who might benefit either by improvement of their symptoms or resolution of their symptoms through the use of tPA?

A. Correct.

Q. So it's not a zero-sum game. It's not you don't get improvement if you don't get tPA and you automatically get improvement if you do get tPA?

A. That's correct.

Q. All right. Continue on.

A. Yes.

Q. Sorry to interrupt you, but I just want to make sure I understand this. If you could continue with the pros and cons.

A. Yes. So the con is that in a subset of people, around 6 percent, the administration of tPA will engender intracranial bleeding usually thought to be coming from damaged brain tissue, and that can be

catastrophic either in killing the patient or in causing increased stroke-like symptoms.

And therefore, it is -- you need to discuss with the patient the fact that this drug has the potential to help them but also the potential to hurt them.

Q. And using the figures you just provided, it sounds like you're talking about a 12 percent chance of improved outcome versus a 6 percent chance of having intracranial bleeding.

A. Yeah. These percentages are on top of what you would expect if you did nothing at all. So even those people who have nothing at all done can go from an ischemic stroke to a hemorrhagic stroke again because -- theoretically because of the death of brain tissue which then leaks blood.

Q. And I've seen reference to that.

Is that where you have an ischemic stroke that damages blood vessels and then when you get a reperfusion of blood into that area, it can burst through some of those damaged blood vessels?

A. Yes, either burst through the blood vessels or just the tissue itself has lost its integrity 'cause it's now dead tissue and it just falls apart and the small blood vessels in there fall apart with it.

Q. All right. And just so that I can follow this along then, you have a pote- -- a stroke patient who's got sort of a baseline risk of -- or baseline probability of either getting better or having a bleed, and you're talking about what the additional pros and cons are for the use of tPA, correct?

A. Correct.

Q. And I don't want to go back through the testimony, but you've got this percentage of possibility that it might improve his condition, and you've got a percentage that it might cause him to suffer a dangerous bleed in his brain, correct?

A. Correct.

Q. All right. And again, I apologize for interrupting you, but I want to follow this along; and if I wait to the end, I'll forget my question.

Can you continue, please, discussing what the pros and cons are that you would present?

A. Yeah. And so the other issue, then, is how debilitating is this stroke. Do you want -- or could you live comfortably with the disability that you're now presenting with in the emergency department, or would you find that to be a real problem for you and your lifestyle; and therefore, are you willing to try this drug with the hope that it will ameliorate the problem

My understanding is it is something like 40 minutes. And there are a number of contraindications to doing MRI which precludes everybody's being able to be put into the scanner.

Therefore, the CT scan is the preferred modality. The MRI actually will see a stroke earlier on than a CT scan will, but both CT and MR will see bleeds about equally well. Since the initial imaging is done primarily to answer the question "is there a bleed or isn't there a bleed," that makes the CT scan the preferred modality.

Q. So the time that you can do the CT scan makes it the preferred test because you're basically looking to see if the patient has an ischemic stroke or a hemorrhagic stroke?

A. Correct.

Q. And I think you said this before, but I just want to make sure I followed you.

If the patient has a hemorrhagic stroke, then that would be a contraindication for giving tPA?

A. Correct.

Q. All right. And if you could take a look at page 4 of your report.

A. Yes.

Q. You mentioned several points in your testimony

about the time factor in the decision of whether to use tPA. And in the bottom of the first paragraph on page 4, you state "The use of tPA is a time-dependent issue, and expeditious transfer would be of the highest priority."

Did I read that correctly?

A. Yes.

Q. And if you could turn to page 5 of your report, in the first full paragraph there, the sentence where you state -- or part of a sentence, you state "It was the standard of care to offer it," meaning tPA, "to patients within the first three hours of the onset of stroke symptoms at the time that Mr. Helms had his medical emergency."

Did I read that correctly?

A. Yes.

Q. And so am I interpreting your report correctly that in August of 2008, the standard of care for the treatment of potential stroke patients was to offer them tPA if you could administer it within three hours of the onset of symptoms?

A. Yes.

Q. All right. And so to determine whether Mr. Helms could have been offered tPA under the standard of care in 2008, you would have to start from whatever

time his stroke symptoms began and then work forward three hours and determine whether it would have been possible to diagnose his condition to do what -- the imaging that needed to be done in order to administer the tPA within that three-hour period; is that correct?

A. Correct.

Q. And -- and again, so just that it's clear, if his symptoms started at 5:30 in the morning, then the time window would be until approximately 8:30 in the morning?

A. Correct.

Q. All right. Doctor, pardon me for a moment. I'm going through my notes and crossing off some questions. I'm not ignoring you. I'm just trying to shorten this up a little bit.

A. Okay.

Q. And, Doctor, stated in the converse, if more than three hours had passed between the onset of Mr. Helms' stroke symptoms, then in 2008 the standard of care would be not to administer tPA?

A. Correct.

Q. Now, within that three-hour I'll call it window of treatment for tPA, is the general rule of sooner is better than later -- does that apply?

A. Yes.

Q. And so is it generally correct that if tPA is going to have a beneficial effect, you have a greater chance of it having a beneficial effect if you could administer it to a patient one hour after the symptoms start than if you administer it at two hours and 45 minutes after the symptoms start? Would that be a fair statement?

A. Yes.

Q. And so you want to try and get the patient diagnosed and administer the tPA as soon as possible within this three-hour window, correct?

A. Correct.

Q. All right. Now -- and you talk about the results of the use of tPA, and you've testified about that before. I'm not going to go through all that testimony.

But you use two words that I want to ask some follow-up questions about. You use the word improvement of symptoms and -- versus resolution of symptoms.

Did I hear you correctly?

A. Yes.

Q. And am I interpreting that correctly to mean that if tPA were to work, that in some patients it might improve their symptoms; whereas for other patients, there might be a complete resolution of the symptoms?

Am I --? Is that a fair statement?
A. Yes.
Q. And so you'd agree that there are ranges of outcomes for stroke patients; even if the tPA is effective, there could be a range of positive outcomes, correct?
A. Yes.
Q. And so someone might have a positive response to tPA but only have partial improvement of their symptoms; they might still have some remaining deficits. Would that be a fair statement?
A. Yes.
Q. And some other percentage of patients might be lucky that they would get tPA and have a complete resolution of their symptoms. Would that be fair?
A. Yes.
Q. But at the same time, there are some stroke patients who wouldn't get tPA at all, and they might also have a complete resolution of their symptoms?
A. Yes.
Q. And then there are a number of patients who get tPA, and they don't get any improvement in symptoms. Is that a fair statement?
A. Yes.
Q. All right. And then you made reference to the

some percentage of patients who get tPA, and they actually have bad side effects, that they get cerebral hemorrhage from the administration of tPA. Is that a fair statement?
A. Yes.
Q. All right. Are you able to predict ahead of time which patients will get improvement from tPA and which ones won't?
A. No.
Q. All right. And are you able to predict ahead of time how much improvement the patient might get from tPA?
A. No.
Q. Okay. If you could turn to page 5 of your report.
A. Yes.
Q. And this is the section of your report where you're talking about causation. You started talking about that on page 4, but it continues on to page 5.
Do you see that?
A. Yes.
Q. And you state in the first full paragraph on page 5:
In most areas of medical malpractice law one must show that meeting the standard of

care would probably have resulted in a good outcome; or, conversely, that failing to meet the standard of care probably caused the bad outcome.
Did I read that correctly?
A. Yes.
Q. And that's generally referring to the standard of proof in civil litigation that in order to prove an element, whoever has the burden to prove has to prove that something is more likely than not true. Do you understand that?
A. Yes.
Q. And if it's a medical malpractice claim and the claim is that someone failed to give some treatment, the proof has to be that that treatment more likely than not would have improved or cured the patient's condition. Do you understand that?
A. Yes.
Q. All right. But you then go on to state in your report, "However, the use or non-use of tPA is different. Even under the best of circumstances, using tPA offers only the possibility of stroke symptom reversal, not the probability."
Did I read that correctly?
A. Yes.

Q. And so I don't want to go back through the statistical testimony that you'd given previously; but basically what you are saying in this report is that even if you use tPA, it is not possible to predict that the patient would on a more-likely-than-not basis have an -- had an improved outcome?
A. Correct.
Q. All right. And so you can't render an opinion on a probability basis. You can -- you can only say that using tPA would have the possibility of improving the patient's symptoms.
MR. HELMS: Objection.
BY MR. GUARINO:
Q. Am I correct in that statement?
MR. HELMS: Objection.
THE WITNESS: A. Correct.
MR. GUARINO: And let me be clear. What's the objection, Mr. Helms?
MR. HELMS: You want to repeat your question?
MR. GUARINO: Well, no. I want to know what your objection is before I restate my question.
MR. HELMS: Let's have the court reporter read the question back.
MR. GUARINO: Can you do that, Madam Court Reporter?

Exhibit C
Pages as Marked

THE COURT REPORTER: Yes.
Question: "And so you can't render an opinion on a probability basis. You can -- you can only say that using tPA would have the possibility of improving the patient's symptoms?"
MR. GUARINO: What is your objection to that question, Mr. Helms?
MR. HELMS: It's a two-part question. I think the -- the opinion's already been stated at the end. So you're asking two different questions in one question. You want to break them up?
MR. GUARINO: Madam Court Reporter, did you get the doctor's answer to that question?
THE COURT REPORTER: Let me check.
MR. GUARINO: Sure.
THE COURT REPORTER: There was no answer -- well, there was an objection, and then the answer was "Correct."
MR. GUARINO: All right.
Q. Doctor, let me ask you another question.
Based on your report, then, am I correct in assuming that your opinion is that even if you give tPA to a stroke patient within three hours of the onset of stroke symptoms, you cannot predict with reasonable medical certainty that that will improve their outcome?

A. Correct.
Q. All you can testify to or render an opinion on in this case is that giving tPA to Mr. Helms, if it could have been administered within three hours, might possibly have improved his outcome?
A. Correct.
Q. And by the same token, given your testimony, it might also have caused him to suffer cerebral hemorrhage, correct?
A. Correct.
Q. And just to close up this section of questions, you cannot testify or render an opinion with reasonable medical certainty as to how much improvement a patient like Mr. Helms might get from the administration of tPA; is that correct?
A. Correct.
Q. And -- and then to -- to bring it the specific claims in this case, even if Mr. Helms could have been diagnosed and treated with tPA within three hours of the onset of his stroke symptoms, you cannot testify that his visual deficit would more likely than not have been improved?
A. Correct.
Q. You can only testify and render an opinion that it might possibly have been improved?

A. Correct.
Q. All right. And if the evidence shows that in fact it would have taken longer than three hours to get Mr. Helms to a facility where he could have been diagnosed and administered tPA, then that would have been outside the standard of care, as you understand it, in 2008?
A. Yes.
Q. And to put that in layman's terms, so if it would have taken more than three hours from the onset of Mr. Helms' symptoms to get him assessed and transported to another medical facility, then he would not have been administered tPA because it would have been outside the standard of care, which was three hours in 2008, correct?
A. Correct.
MR. GUARINO: Madam Court Reporter, can we go off record?
THE COURT REPORTER: Yes.
(Whereupon, at 12:03 p.m. a recess is taken until 12:12 p.m.)
MR. GUARINO: Madam Court Reporter, I just want to confirm that I have marked that was marked Exhibits 1, which is a case file; 1-A, which is the additional papers that Dr. Wapen identified as

communications with Mr. Helms; there was -- Exhibit 2 is his report; there are the three attachments which are 3, 4, and 5, the three articles; his CV is Exhibit 6, and there are the three major medical records that are Exhibit 7; am I correct?
THE COURT REPORTER: Let me check.
MR. GUARINO: Yes, please.
(Whereupon, at 12:13 p.m. discussion off record confirming exhibits until 12:15 p.m.)
MR. GUARINO: Can we go back on the record, please?
THE WITNESS: Okay.
THE COURT REPORTER: Yes.
BY MR. GUARINO:
Q. Dr. Wapen, I have your report. I've asked you about some of the statements in your report. I'm not going to cover all the other statements in your report.
But I'd like to know, are there any other opinions that you intend to offer that are written in your report or that we haven't covered in your testimony today?
A. No.
Q. All right. What is your hourly billing charge for the deposition today?

Exhibit C
Pages as Marked